Remarks

At the time of the instant Office Action, claims 1-28, 30-34 and 36 were pending in the subject application; claims 1-6, 12-23, and 34 were withdrawn; and claims 7-11, 24-28, 30-33 and 36 were considered. Applicant notes with appreciation the withdrawal of the previously issued rejection under the first paragraph of 35 U.S.C. § 112 with respect to the term "substantially".[1] By this Amendment, claim 5 is amended to correct a typographical error and claim 37 is newly added to recite with more particularity according to one or more embodiments of Applicant's invention. Support for the claim amendments can be found throughout the application as originally filed, particularly in the original claims 4-5, 15, and 27. No new matter is introduced by these claim amendments. Favorable reconsideration of pending claims 7-11, 24-28, 30-33 and 36 is respectfully requested.

Remarks Directed to Claim Rejections
under 35 U.S.C. § 101

Rejection of the claimed invention under 35 U.S.C. § 101 is maintained for the same reasons set forth in the record.[2] For at least the reasons set forth below, Applicant respectfully traverse the rejection and request the allowance of the claims.

The Examiner has ***not*** properly established a lack of utility rejection under 35 U.S.C. § 101. MPEP 2107.02 (IV) in relevant portion provides that, to properly reject a claimed invention under 35 U.S.C. § 101, the Office ***must*** (A) make a *prima facie* showing that the claimed invention lacks utility, ***and*** (B) provide a ***sufficient evidentiary basis*** for factual assumptions relied upon in establishing the *prima facie* showing. Accordingly, the Office ***must*** do more than merely question operability - it ***must*** set forth factual reasons which would lead

[1] *See* page 2 of the instant Office Action.

[2] *See* pages 2-3 of the instant Office Action, page 3 of the Office Action dated June 24, 2009, and page 3 of the Office Action dated January 7, 2009.

one skilled in the art to question the objective truth of the statement of operability. The *prima facie* showing ***must*** contain the following elements:

> (A) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is neither both specific and substantial nor well-established;
> (B) Support for factual findings relied upon in reaching this conclusion; and
> (C) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

It is ***imperative*** that Office personnel use specificity in setting forth and initial rejection under 35 U.S.C. § 101 and support any factual conclusions made in the *prima facie* showing.

In making and maintaining this lack of utility rejection, the Examiner provides a single paragraph of 73 words as reasons for supporting the rejection. The paragraph is reproduced below:

> The claimed invention lacks patentable utility. The instant application fails to provide adequate evidence to support the utility of the invention. Specifically, there is insufficient evidence to show that a compound which is not released on or into the body can have any medically beneficial effect. Additionally, the agents used to form the liquid impermeable but gas permeable layer (e.g. wax) are also used in the art to form controlled release formulations of drugs.

As can be seen from the above reproduced paragraph, the Examiner sets forth the rejection with a conclusory first sentence of lack of utility, follows with a conclusory second sentence of lack of adequate evidence for supporting the utility. In so doing, the Examiner impermissibly makes and maintains the rejection without meeting the required burden pursuant to relevant portions of MPEP cited above, namely, showing clear explanation for the lack of utility assertion, providing factual findings and support thereof, and providing an evaluation of all relevant evidence of record.

Further, the Examiner has ***not*** been receptive to Applicant's express assertion of utility, nor to arguments and evidence Applicant has submitted for the record thus far. For

instance, Applicant has stated that the claimed invention can be used to reduce symptoms of and/or to treat disorders associated with medical conditions characterized by blockage of exocrine glands including ducts of sweat glands. *See* page 9 of Applicant's Amendment dated April 7, 2009. Note that in most cases, an applicant's assertion of utility creates a ***presumption of utility*** that will be sufficient to satisfy the utility requirement of 35 U.S.C. 101.[3] Where an applicant has specifically asserted that an invention has a particular utility, that assertion ***cannot*** simply be dismissed by Office personnel as being "wrong," even when there may be reason to believe that the assertion is not entirely accurate.[4]

Further, Applicant has provided for the record proposed illustrative mechanisms by which the claimed invention is believed to function. *Id.* In particular, Applicant has proposed that when placed near to or against one's skin or placed intact in one's body, the claimed preparation can be in communication with the skin via gases in the surrounding environment. *Id.* Moreover, Applicant has submitted a Rule 1.132 Declaration by Warren Ward via Applicant's Amendment dated April 7, 2009. Mr. Warren Ward, the inventor and Applicant, clearly states that the EquiwinnerTM patches according to one or more embodiments of the claimed invention have been widely accepted in many countries and well received in the horse trainers community. *See* paragraphs 17 and 18 of the Warren Ward Declaration.

In the "Response to Arguments" on page 5 of the instant Office Action, the Examiner opines that the Warren Ward's Declaration of April 7, 2009 is not sufficient for establishing the utility because, according to the Examiner, recitation of commercial success is irrelevant for overcoming a lack of utility rejection. Applicant respectfully requests that Examiner provide support for this assertion. To the contrary, the Examiner's attention is respectfully directed to MPEP 2107.02 (VI), which in relevant portion provides that an applicant can rebut a lack of utility rejection using ***any*** combination of the following: amendments to the claims, arguments or reasoning, or new evidence submitted in ***an affidavit or declaration under 37 CFR 1.132***, or in a printed publication.

---

[3] *See* MPEP2107.02(I); see also *In re Langer*, 503 F.2d 1380, 183 USPQ 288 (CCPA 1974).

[4] *See* MPEP 2107.02 (III) (B).

Notwithstanding all the above, the Examiner continues to maintain the rejection by asserting that a drug is not released cannot achieve any therapeutic values.[5] According to the Examiner, Applicant's claimed invention is clearly analogous to taking a drug wrapped in non-biodegradable plastic that cannot get degraded inside the body. *Id.* Further, the Examiner asserts that Applicant's claimed invention does not follow the mechanisms of drug binding to its receptors so as to achieve therapeutic effects; and therefore according to the Examiner, Applicant's claimed invention is contrary to the currently accepted scientific principles. *Id.*

With this line of reasoning, it appears that the above-cited Examiner's assertions are founded on the Examiner's belief and/or assumption that the claimed preparation is a drug, and that a drug must be released and must bind to its receptor to be therapeutically effective. It then appears that the lack of utility rejection is founded on the Examiner's belief and/or assumption that an invention must have a conventionally recognized mechanism of action, such as a cell receptor binding, that must not be contrary to the currently accepted scientific principles, to satisfy the utility requirement.

The Examiner has been mis-characterizing the claimed invention. Just as acknowledged by the Examiner[6] that an invention does not have to be a pharmaceutical to have utility, an invention does not have to be released or react with body cell receptors to be useful, contrary to the Examiner's assertions. In fact, Applicant has ***never*** suggested that the claimed invention can only function via cell receptor mediated signaling communication. In fact, as shown in Warren Ward's Declaration of April 07, 2009, at paragraphs 9 and 10, wherein it is stated that changes in external environment in proximity to the body cell surfaces may be calculated to elicit a response. These proposed mechanisms have nothing to do with cell receptor binding or signaling as contended by the Examiner.

Applicant has introduced for the record the published work of *MacKinnon*

---

[5] *See* "Response to Arguments" on pages 3-5 of the instant Office Action.

[6] *See* the "Response to Arguments" on page 3 of the instant Office Action.

wherein sodium is said to have a similar action to potassium i.e. proximity of both these ions to ion channels activates electrical signals. This is the effect described in the specification at paras 0066 and 0067 "to provide in the air and in the liquid environment of the body an amount of sodium, which appears to indicate a surplus". No binding to receptors is suggested to be involved.

Moreover, many substance illustrated in the Examples section of the original specification are known to be capable of functioning independently of any receptor binding mechanisms. Insulin is a substance which does bind to receptors. However the current scientific opinion is that the presence of metformin (used in example 2) influences the insulin receptors, however, there is no suggestion anywhere in current literature that metformin binds to receptors. See also Li et al., submitted herewith as Exhibit 4B, states on page 59 that the effect of metformin n insulin signal transduction represents a primary mechanism of metformin action in insulin state. On the contrary metformin is a substance which, when present, influences signalling. Submitted herewith as Exhibit 4A, Goodmans at page 1705 para 3 states that Metformin "is excreted unchanged in the urine". It cannot both bind to receptors and be excreted unchanged in the urine. Smart et al., submitted herewith as Exhibit 4C, states at page 229 that capsaicin (used in example 1) is well known to influence but not bind to the vanilloid receptor (VR1).

For at least the reasons set forth above, reversal of this rejection is respectfully solicited.

Remarks Directed to Claim
Rejections under 35 U.S.C. § 112

Rejection of claims 7-11, 24-28, 30-33 and 35-36 under 35 U.S.C. § 112, first paragraph, for failing the enablement requirement, is maintained for similar reasons set forth previously in the record.[7] Applicant's previously submitted remarks are not reproduced herein.

[7] *See* pages 5-8 of the instant Office Action, pages 5-8 of the Office Action dated June 24, 2009, and *see* also pages 4-5 of the Office Action dated January 9, 2009.

However, Applicant wishes to comment on the Examiner's "Response to Arguments."[8]

The Examiner continues to opine that Applicant's claimed invention lacks enablement as there lacks evidence to show a drug not released is effective in producing any medical effect.[9] Applicant respectfully traverses for at least the reasons set forth previously for the record.[10]

In addition, Applicant respectfully submit the following. As stated in paragraphs 21 to 32 of Warren Ward's Declaration submitted herewith, Mr. Warren Ward states that sodium chloride as enclosed within the liquid impermeable but gas permeable layer, constructed according to one or more embodiments of the claimed invention, does affect its immediate surrounding environment without the preparation of the invention being changed in any way. The effect on the surrounding metals is solely the result of the construction of the spheres is demonstrated by the observation that a similar amount of sodium chloride to that included in the spheres and cylinders, when dissolved in water has no corrosive effect on the metals. It should be noted that the same two spheres containing coated sodium chloride were used for periods of 48 hours then 48 hours then 24 hours in water without being changed in any way. It should additionally be noted that if the sodium chloride had escaped from the coating this could not be responsible for the action on the metals, only the sodium chloride within the layer had that action. Also if the sodium chloride had escaped from the coating then both the spheres and the cylinders would have floated away from the metal in each case. This did not happen as stated herein above. The tests further support the asserted notion that water molecules are adjacent to the medically efficacious substance through the gas permeable liquid impermeable coating.

Rejection of claims 7-11, 24-28, 30-33 and 35-36 is maintained under 35 U.S.C.

---

[8] *See* pages 8-10 of the instant Office Action.

[9] *See* page 5 of the instant Office Action, page 5 of the Office Action dated June 24, 2009.

[10] *See* pages 10-12 of Applicant Amendment dated September 23, 2009, and pages 17-19 of Applicant's Amendment dated April 7, 2009.

§ 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.[11] In maintaining the rejection, the Examiner continues to argue that the claim language recite a preparation for use as a medicament, wherein the agent is prevented from release. It is not clear, according to the Examiner, whether the instantly claimed invention is pharmaceutical formulation since it is prevented from being released. These assertions have been addressed herein above, which are not reproduced for brevity. In brief, the claimed preparation does not have to be a pharmaceutical, nor does the claimed preparation depend on release of the encapsulated substance to be released for therapeutic action. In one example, the encapsulated substance can function via effecting surrounding environment and inducing changes in the vicinity.

For at least the reasons set forth above, reversal of rejection under 35 U.S.C. § 112 is respectfully solicited.

Remarks Directed to Newly Added Claim 37

Claim 37 is newly added to depend from claim 24 and provide additional features. In particular, claim 37 recites that the preparation of claim 24 prepared as a patch, having two spaced apart spheres, each of a diameter of 1 mm to 10 mm, wherein the aqueous liquid impermeable and gas permeable layer contains a beeswax hardened with cornstarch and talc. As stated in paragraphs 12 to 17 of Warren Ward's Declaration submitted herewith, the Equiwinner™ patches as recited in claim 37 has gained widely recognized acceptance. Moreover, as stated in paragraphs 18 to 19 of Warren Ward's Declaration submitted herewith, a UK veterinarian Dr. Steve Gittins and an Italian veterinarian Dr. Paola Gulden both reported positive medical effects of the said supplied Equiwinner™ patches. Allowance of the new claim 37 is respectfully solicited.

[11] *See* pages 9-10 of the instant Office Action.

CONCLUSION

Applicant submits that the claims are now in condition for allowance, and respectfully requests a Notice to that effect. If the Examiner believes that further discussion will advance the prosecution of the application, the Examiner is highly encouraged to telephone Applicant's attorney at the number given below.

Please charge the extension of time fee and any fees or credit any overpayments as a result of the filing of this paper to our Deposit Account No. 02-3978.

Respectfully submitted,

WARREN WARD

By /Junqi Hang/
Junqi Hang
Reg. No. 54,615
Attorney for Applicant

Date: April 5, 2010

BROOKS KUSHMAN P.C.
1000 Town Center, 22nd Floor
Southfield, MI 48075-1238
Phone: 248-358-4400
Fax: 248-358-3351